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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,777	09/21/2001	Suzanne V. Smith	11184.00002	8748
22908	7590	10/16/2003	EXAMINER	
BANNER & WITCOFF, LTD. TEN SOUTH WACKER DRIVE SUITE 3000 CHICAGO, IL 60606			HARTLEY, MICHAEL G	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 10/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/869,777

Applicant(s)

SMITH ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,8-14,17,18,21 and 24-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-14,17,18,21 and 24-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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***Response to Amendment***

The amendment filed 8/18/2003 has been entered.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-6, 8, 9, 24-27, 39, 40, 43-45 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcuccio (WO 95/31202), for the reasons set forth in the office action mailed 3/18/2003.

Applicant's arguments filed 8/18/2003 have been fully considered but they are not persuasive.

Applicant asserts that Marcuccio is limited to cobalt containing ligands because on page 27, Marcuccio lists various publications describing processes which may be employed for preparing the compounds, and the most recent publication (Bottomley) describes a method of preparing cobalt complexes.

This is not found persuasive because Marcuccio teaches compounds of a broader scope than encompassed by a citation of background methods of making the compounds, as asserted. Clearly, Marcuccio discloses a broader scope than set forth in this reference to background art. Marcuccio discloses compounds of formula 1 and 2 on pages 4-7, as well as, methods of preparing such compounds, see pages 27+. Complexes with other metals than cobalt are disclosed, as shown on page 8. In response to applicant's arguments concerning the Bottomley reference, it is noted that the Bottomley reference was not relied upon in the rejection, but the Marcuccio reference was used, which may be relied on for all that it teaches. The relevance of this argument is also not seen for many of the claims, as many of the claims do not exclude cobalt complexes, for example, claim 1 would not exclude cobalt complexes and cobalt is specifically recited in claims 32, 33, 40, 41, 45 and 46.

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Applicant further asserts that, in contrast to Marcuccio, the present invention provides metal free ligands which are functionalized.

This is not found persuasive because with regard to the assertion of metal free ligands, this is not seen, as the claims clearly encompass metal chelates, see for example, claims 8-10. Claim 1 cannot be said to exclude metal chelates when a claim dependent thereon recites metal chelates. Further, Marcuccio discloses free metal chelating agents on page 7 in formula 2. With regard to the term, functionalized, it is noted that since the chelates disclosed by Marcuccio may have the same structure, they must have the same functionality, e.g., be functionalized. Also, the claims state "capable of binding said compound of formula (I) to a molecular recognition unit" (MRU). A recitation that any element is "capable of" is not a positive recitation in any patentable sense but only requires the ability to so perform. See *In re Hutchison*, 69 USPQ 138. Clearly, the various side groups on the chelates disclosed by Marcuccio are capable of performing binding a MRU, as almost any chemical moiety can be chemically modified to bind to some type of targeting agent. Also, applicant describes an MRU to include a carbohydrate on page 5 of the specification and Marcuccio teaches that the chelates may have a sugar moiety as a substituent (see page 5), thus, the chelates disclosed by Marcuccio include a MRU as claimed.

Applicant also asserts that the claimed chelates have unexpected advantages. However, this is not found persuasive since the data is neither a comparison with the closest prior art nor commensurate in scope with the instant claims, as only a single ligand with a single metal at a certain pH is stated to have formed a complex with a metal in 1 min. There is nothing to which this complex formation has been compared to for showing an unexpected advantage and no showing to suggest that this asserted unexpected advantage would hold over the scope of the claims.

Claims 1, 2, 4-6 and 8-14, 17, 18, 21, 24-29 and 39-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcuccio (WO 95/31202) in view of Alvarez (US 4,741,900), for the reasons set forth in the office action mailed 3/18/2003.

Applicant's arguments filed 8/18/2003 have been fully considered but they are not persuasive.

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Applicant asserts that there is no motivation to combine the references.

This is not found persuasive because both Marcuccio and Alvarez disclose cryptate compounds having the same utilities, e.g., as in vivo diagnostic agents. Alvarez discloses radiopharmaceutical compositions for diagnostic or therapeutic methods comprising radiometal complexes and it is well known in the art that these ligands may bind various metals in an equivalent manner, as shown by both Marcuccio and Alvarez. It is further known in the art that chelates for diagnostics may complex a radiometal in an equivalent manner to a non-radiometal and that the use of a radiometal provides the advantage of being useful in radioimaging, as shown by Alvarez.

Applicant's arguments with respect to claims 1-6, 8-14, 17, 18, 21 and 24-48 have been considered but are moot in view of the following new ground(s) of rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-14, 17, 18, 21 and 24-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claims 1, 25, 44 and 48, the recitation that was added to define R<sup>6</sup> as OH was not described in the specification. Nowhere in the specification is it seen wherein R<sup>6</sup> was defined to include OH. In fact, the only description found for R<sup>6</sup> is in original claim 1, which does not state that R<sup>6</sup> may be OH.

In claim 8, the recitation of a metal "other than cobalt" was not described in the specification to show that applicant envisioned this specific exclusion at the time of filing.

In claim 25, the two exclusionary recitations which state "with the proviso" were not described in the specification. There is nothing to show that these specific exclusions were envisioned at the time of filing.

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It is noted that any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983) aff'd mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.

The dependent claims fall therewith.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Adding the recitations as set forth which includes reference to variable R<sup>6</sup> to the specification as supported by any original claims, e.g., claim 1.

### ***Allowable Subject Matter***

Claims 3 and 30-38 are free of the art of record, and would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and to overcome the rejections under 35 USC 112. However, it is noted that in order for claim 3 to be allowable (e.g., by including the limitations of claim 1), this claim must be further amended to recite at least one X or Y is C-Z, as it is the groups for Z in claim 3 which differentiate this claim over the prior art.

### ***Conclusion***

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date

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of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Michael G. Hartley  
Primary Examiner  
Art Unit 1616

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